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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,516	09/15/2000	Gary A. Beaudry	GA0129C	2805

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GENZYME CORPORATION
LEGAL DEPARTMENT
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EXAMINER
MYERS, CARLA J

ART UNIT	PAPER NUMBER
1634	15

DATE MAILED: 11/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/663,516	BEAUDRY ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *1-20 and 23-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Applicant's election of group VI and SEQ ID NO: 35 with respect to claims 21 and 22 in Paper No.13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The specification is objected to because the assigned SEQ ID NOs have not been used to identify each sequence listed, as required under 37 CFR §1.821(d). See, for example, page 19 of the specification.

3. Claims 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 21 and 22 are drawn to a method for detecting a lung cancer cell wherein said methods comprise contacting a sample suspected of containing a lung cancer cell with an agent that binds to a peptide produced by a larger or full-length fragment containing the polynucleotide of SEQ ID NO: 35 and detecting any peptide:agent complex as indicative of the presence of a lung cancer cell. The specification teaches methods of performing SAGE to detect the presence of nucleic acids expressed in lung cancer cells. In particular, the specification teaches that the 10 mer of SEQ ID NO: 35 is expressed in lung cancer cells (see Table II). The specification (page 49) also states that "Table I and II summarize the comparative SAGE analyses of cDNA clones derived from the lung cancers of two individuals and the lungs of two normal individuals."

However, the specification does not provide any data concerning the expression of peptides encoded by this 10 mer fragment and does not provide any information as to the whether the 10 mer fragments or peptides encoded by said fragments are present in other types of normal cells. There is no evidence provided in the specification to indicate that the 10 mer fragment is exclusively expressed in lung cancer cells. Thereby it has not been established that the presence of peptides encoded by the 10 mer fragment would be diagnostic of the presence of lung cancer cells. It is highly unpredictable as to whether a fragment encoding only 3 amino acids could be used to detect the presence of lung cancer cells. The claims are further inclusive of using agents which bind to "a gene product produced from a polynucleotide comprising a polynucleotide sequence obtained by identification of larger fragment or full length coding sequence" of SEQ ID NO: 35. However, the specification has not identified any larger length or full length nucleic acids comprising SEQ ID NO: 35 which are specifically expressed by lung cancer cells, such that the presence of the encoded peptide would distinguish lung cancer cells from other types of cells. The identification of larger length or full length polynucleotides comprising SEQ ID NO: 35 constitutes a research project. Accordingly, it would require undue experimentation to practice the claimed invention because this would necessitate screening the human genome and the genomes of other organisms for the presence of nucleic acids which comprise SEQ ID NO: 35, isolating the larger length or full length molecules, and assaying such molecules to determine whether they encode for proteins which are specifically expressed in lung cancer cells and not expressed in normal cells. The specification does not provide any information regarding the

length, structure or functional activity of the larger or full-length polynucleotide or the peptide encoded thereby. Case law has established that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement" (*Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001). In the instant case, the specification has not fulfilled this requirement because the specification has not taught or provided adequate guidance for one to obtain full length or larger length molecules comprising SEQ ID NO: 35 and has not adequately taught one of skill in the art how to detect the presence of a lung cancer cell by detecting a peptide encoded by a larger length or full length molecule comprising SEQ ID NO: 35.

4. Claims 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 21 and 22 are drawn to a method for detecting a lung cancer cell wherein said methods comprise contacting a sample suspected of containing a lung cancer cell with an agent that binds to a peptide produced by a larger or full-length fragment containing the polynucleotide of SEQ ID NO: 35 and detecting any peptide:agent complex as indicative of the presence of a lung cancer cell. While isolated nucleic acids consisting of the sequence of SEQ ID NO: 35 meet the written description requirements of 35 U.S.C. 112, first paragraph, the specification does not disclose and fully characterize the claimed genus of polynucleotide sequences "comprising a

polynucleotide sequence obtained by identification of larger fragment or full length coding sequences" of SEQ ID NO: 35 . *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". Accordingly, knowledge of the sequence of the 10 mer fragment of SEQ ID NO: 35 does not allow the skilled artisan to envision all of the contemplated larger and full-length nucleic acids comprising SEQ ID NO: 35. The claimed polynucleotides have not been sufficiently described in terms of their structural properties (length, identity of flanking nucleotide sequences, etc) or functional properties (e.g., activity of the encoded peptide). The specification does not teach any members

of the genus of molecules of larger fragment or full-length molecules comprising SEQ ID NO: 35. Accordingly, Applicants have not provided sufficient evidence that they were in possession, at the time of filing, of the invention as it is broadly claimed and thus the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

5. Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 22 are indefinite over the recitation of "detecting any agent:peptide complex so formed". While the claims previously refer to a gene product, the claims do not previously refer to peptide. Therefore, it is unclear as to how the step of detecting the agent: peptide complex relates to the remainder of the claim. This rejection may be overcome by amendment of claim 21 to recite "agent that specifically binds to a **peptide** produced from a polynucleotide..."

6. Claims 21 and 22 are allowable over the prior art because the prior art does not teach methods for detecting a lung cancer cell by detecting a peptide encoded by a polynucleotide comprising SEQ ID NO: 35.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

CARLA J. MYERS
PRIMARY EXAMINER